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| FORM PTO-1390 (REV. 12-97) | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | 74 RECEIVED PCT/PTO 21 JUL 1998 ATTORNEY'S DOCKET NUMBER 20253-60398 | |
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | | | U.S. APPLICATION NO. (If known, see 37 CFR 1.5) Unknown | |
| INTERNATIONAL APPLICATION NO. PCT/AU97/00259 | | INTERNATIONAL FILING DATE 29 April 1997 (29.04.97) | | PRIORITY DATE CLAIMED 30 April 1996 | |
| TITLE OF INVENTION CONTAINER FOR SHARP INSTRUMENTS | | | | | |
| APPLICANT(S) FOR DO/EO/US CAVANAGH, Michael Shane | | | | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | | | | |
| 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). 4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau). b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau). b. <input type="checkbox"/> have been transmitted by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)). 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> A translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | | | | |
| Items 11. to 16. below concern document(s) or information included: | | | | | |
| 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 14. <input type="checkbox"/> A substitute specification. 15. <input type="checkbox"/> A change of power of attorney and/or address letter. 16. <input checked="" type="checkbox"/> Other items or information: 1. Copy of PCT Published Application No. WO 97/40753 with PCT International Preliminary Examination Report 2. Copy of PCT International Preliminary Examination Report with Annexes Attached 3. Verified Statement (Declaration) Claiming Small Entity Status (37 CFR 1.9(f) and (1.27(b))--Independent Inventor | | | | | |

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(317) 236-1313PATENT APPLICATIONIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| <i>Group:</i> | Unknown | } | <u>Certificate Under 37 CFR 1.10</u> |
| <i>Attorney</i> | | } | Express Mail Label No. <u>EM463916681US</u> |
| <i>Docket:</i> | 20253-60398 | } | Date of Deposit: <u>21</u> July 1998 |
| <i>Applicant:</i> | CAVANAGH, Michael Shane | } | I hereby certify that this paper or fee is being |
| <i>Invention:</i> | CONTAINER FOR SHARP INSTRUMENTS | } | deposited with the United States Postal Service's |
| | | } | "Express Mail Post Office to Addressee" service |
| | | } | under 37 CFR 1.10 on the date indicated above and is |
| | | } | addressed to the Assistant Commissioner for Patents, |
| | | } | Washington, D.C. 20231 |
| <i>U.S. Serial No:</i> | Unknown | } | <u>Mary Jean Eskridge</u> |
| <i>International Serial No:</i> | PCT/AU97/00259 | } | Typed or Printed Name of Person Mailing Paper or |
| <i>International Filing Date:</i> | 29 April 1997 (29.04.97) | } | Fee |
| <i>Earliest Priority Date:</i> | 30 April 1996 (30.04.96) | } | <u>Mary Jean Eskridge</u> |
| <i>Examiner:</i> | Unknown | } | Signature of Person Mailing Paper or Fee |

FIRST PRELIMINARY AMENDMENT

Attention: DO/EO/US
Box PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Preliminary to the examination of the above-identified national patent application submitted herewith, applicant respectfully requests entry of the following amendment.

In the Description

After the title, please insert the following paragraph:

--Cross-References to Related Applications

This application is a U.S. national application of international application serial No. PCT/AU97/00259 filed April 29, 1997, which claims priority to Australian (AU) Serial No. PN 9597 filed April 30, 1996.--

In the Claims

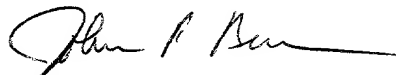
Please amend claim 14 as follows:

14. (Amended) A container as claimed in claim 12[, and including a container as claimed in claim 13.] and adapted to contain a straight needle and a suture threaded thereto; wherein said instrument recess is elongated and closed at one end and adapted to receive said straight needle, and including a suture recess for receiving said suture.

REMARKS

This Preliminary Amendment is being submitted to indicate the relationship of the subject U.S. national application to previously filed applications as required under 37 C.F.R. 1.78, and to delete a multiple dependent claim. With the entry of the foregoing amendments, the application is believed to be in condition for examination and allowance. Consideration of the claims, leading to their allowance and passage of the application to issuance, is respectfully requested.

Respectfully submitted,



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"CONTAINER"

Technical Field

This invention relates to containers.

5 The invention has particular but not exclusive application to containers such as trays for use in surgical procedures for holding a sharp instrument having a cutting portion.

As used herein the expression "sharp instrument" includes equipment which can cut, puncture or otherwise be invasive such as scalpels, needles and other sharp or pointed surgical instruments. The expression "cutting portion" is to be taken to include any surface, edge or point which cuts, punctures or is otherwise invasive and includes a scalpel blade and a needle point.

Background of Invention

During an operation, a scalpel is transferred between surgeon and scrub nurse or other assistant either directly from hand to hand, or more frequently by one person placing it in a tray for the other to pick up. The tray currently used for this purpose is an open topped kidney shaped dish which provides users with no protection against accidental injury from the scalpel blade. Many other instruments such as suture needles and Veress needles are passed directly between the surgeon and scrub nurse or other assistant.

The present invention aims to provide an alternative to known containers, systems and methods for the handling of sharp instruments during surgical procedures.

Summary of Invention

This invention in one aspect resides broadly in a container for holding a sharp instrument having a handle portion and a cutting portion, the sharp instrument being held within the container to be easily accessible during surgical procedures, the container including:-

an instrument recess adapted to receive at least the

cutting portion of the sharp instrument, and

inclined guide means for guiding a sharp instrument placed in the container to the instrument recess;

the arrangement being such that a sharp instrument, received within the instrument recess is positioned therein to be easily accessible for re-use during surgical procedures and such that the cutting portion thereof is not directed towards the opening of the instrument recess whereby a user's fingers are substantially prevented from contacting the cutting portion.

The guide means may converge toward the instrument recess and in a preferred embodiment the container includes inclined walls converging to the opening, the inclined walls constituting the guide means.

In one embodiment the instrument recess is elongated and closed at each end, is adapted to receive a scalpel and along two opposite lengths thereof has a cross sectional configuration of width slightly greater than the major cross-sectional dimension of a scalpel and depth slightly greater than the minor cross-sectional dimension of a scalpel, the length of the instrument recess being such that the scalpel blade is located within one of the opposite lengths irrespective of the position of the scalpel in the instrument recess.

It is preferred that the instrument recess has sidewalls and a base, the junctions thereof being radiussed such that a scalpel is disposed to rest in the recess with its major cross-sectional dimension parallel to the base.

The container may include access means for providing a user with access to the scalpel handle for removing the scalpel from the instrument recess.

The access means could be a pivoting lever arrangement adapted to elevate the scalpel handle portion or alternatively a portion of the container sidewall can pivot to achieve this effect. However the access means is preferably a finger access recess, the cross sectional

configuration of the finger access recess being such as to allow a user's fingers to contact the scalpel handle for removing the scalpel from the instrument recess, the position of the finger access recess being such that the
5 scalpel blade is not located within the finger access recess irrespective of the position of the scalpel in the instrument recess.

The container may include barrier means for preventing a user's fingers entering the instrument
10 recess. The barrier means may constitute the opening to the instrument recess, the width of the opening being such as to allow a scalpel to enter the recess but to prevent a user's fingers entering the recess.

In one preferred embodiment the container may
15 include handle means whereby a user can hold the container. Alternatively, the container may include handle mounting means for mounting a detachable handle whereby a user can hold the container.

In another embodiment the container has a plurality
20 of the instrument recesses each adapted to receive a scalpel therein.

In a further embodiment the container is adapted to contain a suture needle holder and a suturing needle held thereby, and the instrument recess is substantially semi-
25 cylindrical and adapted to receive the suturing needle.

In an alternative embodiment the container is adapted to contain a straight needle and a suture threaded thereto, and the instrument recess is elongated and closed at one end and adapted to receive the straight
30 needle, the container also including a suture recess for receiving the suture. This arrangement may also be included in the container adapted to contain a suture needle holder and a suturing needle.

In another aspect this invention resides broadly in
35 a container for holding a scalpel during surgical procedures, the container including:-

an elongated scalpel recess closed at each end and adapted to receive a scalpel, and having two opposite

lengths of cross-sectional configuration with width slightly greater than that of the major cross-sectional dimension of the scalpel and depth slightly greater than that of the minor cross-sectional dimension of the scalpel, the length of the scalpel recess being such that the scalpel blade is located within one of the opposite lengths irrespective of the position of the scalpel in the scalpel recess, and

guide means for guiding a scalpel placed in the container to the scalpel recess;

the arrangement being such that a scalpel received within the scalpel recess is positioned therein such that the scalpel blade is not directed towards the opening of the scalpel recess whereby a user's fingers are substantially prevented from contacting the scalpel blade.

In a further aspect this invention resides broadly in a container for holding a suture needle holder and a suturing needle held thereby during surgical procedures, the container including:-

a substantially semi-cylindrical needle recess adapted to receive the suturing needle therein, and

guide means for guiding a suturing needle held by a suture needle holder to the needle recess;

the arrangement being such that a suturing needle received within the needle recess is positioned therein such that the point of the suturing needle is positioned within the needle recess such that a user's fingers are substantially prevented from contacting the point.

In another aspect this invention also resides broadly in a container for holding a straight needle and a suture threaded thereto, the straight needle and threaded suture being held within the container to be easily accessible during surgical procedures, the container including:-

an elongated needle recess closed at one end and adapted to receive a straight needle therein;

a suture recess for receiving the suture, and

inclined guide means for guiding a straight needle placed in the container to the needle recess;

the arrangement being such that a straight needle received within the needle recess is positioned therein, to be easily accessible for re-use during surgical procedures and such that the point of the straight needle is positioned within the needle recess such that a user's fingers are substantially prevented from contacting the point.

10 In another aspect this invention resides broadly in a method of transferring a sharp instrument having a handle portion and a cutting portion between operators during a surgical procedure, wherein:-

the transferor of the sharp instrument places the sharp instrument in an instrument recess in an instrument holding container, the sharp instrument being held within the container to be easily accessible during surgical procedures, and

the receiver or transferee of the sharp instrument removes the sharp instrument from the instrument recess;

the instrument recess being adapted to receive at least the cutting portion of the sharp instrument, and the instrument holding container having inclined guide means for guiding a sharp instrument placed therein to the instrument recess, the arrangement being such that a sharp instrument received within the instrument recess is positioned therein to be easily accessible for re-use during surgical procedures and such that the cutting portion thereof is not directed towards the opening of the instrument recess whereby an operator's fingers are substantially prevented from contacting the cutting portion.

Description of Drawings

35 In order that this invention may be more easily understood and put into practical effect, reference will now be made to the accompanying drawings which illustrate a preferred embodiment of the invention, wherein:-

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FIGS 1 and 1A respectively are perspective and plan views of a container in accordance with the invention for holding a scalpel;

5 FIGS 2 and 2A respectively are perspective and plan views of a container in accordance with the invention for holding a plurality of scalpels;

10 FIGS 3 and 3A respectively are perspective and plan views of a container in accordance with the invention for holding a suturing needle holder and a suture needle held thereby;

FIGS 4 and 4A respectively are perspective and plan

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views of a container in accordance with the invention for holding a straight needle and threaded suture;

FIGS 5A to 5E illustrate another embodiment of a container for a scalpel which has a mounting for a handle
5 the illustrations being plan, end, side, end and base elevations respectively;

FIGS 6A to 6C are cross-sectional elevations at sections AA, BB and CC as indicated in FIG 5A;

FIGS 7A and 7B correspond to FIGS 5A and 6A
10 respectively and illustrate a handle mounted in the end mounting bracket mounting;

FIGS 8A to 8C are sectional elevations illustrating another embodiment of the scalpel tray with integral handles formed at an end and side, the sectional
15 elevations corresponding with the sections AA, BB and CC indicated in FIG 5A, and

FIGS 9 and 10 illustrate cross-sectional elevations of alternatively shaped recesses for receiving a scalpel.

20 Description of Preferred Embodiment of Invention

FIGS 1 and 1A illustrate a first embodiment of a container 11 for safely containing a scalpel 12 having a handle 13 and blade 14. Container 11 has an elongated recess 15 which is closed at each end 16,17 and receives
25 scalpel 12 as seen in FIG 1A. Scalpel recess 15 has two opposite portions 18 and 19. The width of scalpel recess 15 is slightly greater than that of the major cross-sectional dimension of scalpel 12 (the dimension along the cutting axis, usually the depth of handle 13) and the
30 depth of scalpel recess 15 is slightly greater than that of the minor cross-sectional dimension of the scalpel (usually the width of handle 13).

Sloping side walls 20,21 constitute guide means which guide scalpel 12 when placed in placed in container
35 11 toward scalpel recess 15. Sloping end walls 22,23 also guide the scalpel to toward the scalpel recess.

Intermediate opposite portions 18,19 of scalpel recess 15, finger access recess 24 provides a user with

access to scalpel handle 13 for removing scalpel 12 from
scalpel recess 15. Finger access recess 24 has a cross
sectional configuration such as to allow a user's fingers
to contact the scalpel handle for removing the scalpel
5 from the scalpel recess. Finger access recess 24 is
positioned along scalpel recess 15 such that scalpel
blade 14 is not located within finger access recess 24
irrespective of the position of scalpel 12 in scalpel
recess 15. Moreover the length of scalpel recess 15 is
10 such that scalpel blade 14 is located within one of
portions 18,19 irrespective of the position of scalpel 12
in scalpel recess 15 and irrespective of the type of
scalpel being used.

Thus the shortest of the available blade and handle
15 combinations, which will of course have the largest fore
and aft movement in the recess, will still have its sharp
blade positioned outside the central finger access
recess.

By suitably configuring the length of scalpel recess
20 15 and the length of finger access recess 24, container
11 is designed to have a universality accommodating all
scalpels in a manner such that a scalpel received within
the scalpel recess is positioned therein such that the
cutting edge of scalpel blade 14 is located in finger
25 access recess 24, and is not directed towards the opening
or upper entrance of scalpel recess 15. Accordingly a
user's fingers are substantially prevented from
contacting scalpel blade 14.

The downwardly sloping side and end walls mean that
30 the less precision is required by users when replacing
the scalpel in the container. The downwardly sloping
side walls, and also the end walls, direct the scalpel
positively toward the scalpel recess. Both scalpel
blades and scalpel handles are wider than they are thick,
35 and the scalpel is thus disposed to come to rest in a
flat position in the base of the scalpel recess. In this
position the sharp scalpel blade is below the upper edge
of the scalpel recess. The low centre of gravity of the

container and its relatively wide base provide stability on uneven surfaces such as when placed on a patient's person during a surgical procedure or operation.

FIGS 5A to 5E are plan, end, side, end and base elevations respectively of an alternative container 25 for a scalpel. FIGS 6A to 6C are cross-sectional elevations at sections AA, BB and CC as indicated in FIG 5A. It can be seen that the finger access recess 26 of container 25 has sloping side walls 27,28 and opposed sloping end walls 29,30 and 80,31 on either side of scalpel recess 32. The base 33 of finger access recess 26 extends below the base 34 of scalpel recess 32 to better facilitate the removal from container 25 of a scalpel resting in scalpel recess 32.

One end and one side of container 25 each have a mounting assembly 35 for receiving therein and mounting a handle 36 (as seen in FIGS 7A and 7B). Mounting assembly 35 has a cut out slot 37 in a recessed end or side wall 38 which can receive the locking lip 39 of handle 36 as best seen in FIG 7B. A stub portion 40 of handle 36 then sits in heel 41 where recessed end or side wall portion 38 steps out to meet main end or side wall portion 42.

Alternatively, as seen in FIGS 8A to 8C, container 43 may be integrally provided with end and side handles 44 and 45.

As can be seen in FIG 9, the sidewalls 46,47 of the scalpel recess 81 can be radiussed at 48,49 to the base 50 of the recess such that a scalpel is disposed to rest in the recess with its major cross-sectional dimension parallel to the base. This even further reduces the already statistically remote possibility that a scalpel will fall into the recess and come to rest with the back of the handle in the junction between the recess sidewall and base and consequently with the scalpel blade uppermost.

In another embodiment seen in FIG 10, the container can be provided with a barrier for preventing a user's fingers entering the instrument recess. The barrier is

formed by narrowing the opening or entrance neck 51 of scalpel recess 52 so that the width of the opening is such as to allow a scalpel to enter the recess as it slides along the flat of the scalpel handle down the sloping sidewalls 53,54 towards neck 51, but to prevent a user's fingers entering the recess.

The upper edges of the recess sidewalls 55,56 are gently sloped and radiussed towards neck 51 so that when a scalpel is being removed from the tray under the action of a user's fingers, the flat of the handle will slide upwardly over one of recess sidewalls 55,56 so that it presents to neck 51 with its narrow handle width transverse to the opening.

FIGS 2 and 2A respectively illustrate a container 57 for holding more than one scalpel and has a plurality of the recesses 58-61 each adapted to receive a scalpel. The multiple scalpel container has a raised section 62 located beneath that portion of the container which will contain the scalpel handles. This allows the user to safely grasp the handle and remove or replace the scalpel blade and its handle into the tray. The recessed area for the scalpel blade minimises the chance of the user accidentally injuring themselves on the sharp scalpel blade. The raised edge wall 63,64 located behind the blade handles combines with the endwall 65 to limit fore and aft movement of a scalpel in a manner described above to minimise the potential of the blade coming into contact with the user's fingers. This provides safety for the user when grasping the handle to remove the scalpels from the tray. Raised section 62 beneath the scalpel handle elevates the handle above the main baseplate section and provides sufficient room for a user to grasp the handle when removing the scalpel.

The tray illustrated stores up to four blades and their handles, two long and two short handles fitted with a variety of scalpel blades. The unit also features a recessed area for the safe storage of long Veress needles 66 used for the introduction of gas into the abdominal

cavity for visualisation of the abdominal and pelvic cavities during surgical operations. The tray will prove useful where more than one scalpel blade is used during a surgical operation as it provides a safe means of storing scalpel blades when they are not in use. The majority of surgical operations require the use of more than one scalpel blade. The tray has a low centre of gravity and being of substantially square shape is stable when positioned on an instrument trolley, thereby reducing the risk of its contents falling out and causing injury.

FIGS 3 and 3A illustrate a container 67 for holding a suturing needle holder 68 and a suture needle 69. Container 67 has a substantially semi-cylindrical recess 70 adapted to receive suturing needle 69. Container 67 has a pair of downwardly converging side walls 71, 72 on either side of ramp 73 which constitute guide means for guiding suturing needle 69 held by holder 68 to needle recess 70. The arrangement is such that the substantially semi-circular suturing needles 69 are received within needle recess 70 and positioned therein such that the point of the suturing needle is positioned within recess 70 such that a user's fingers are substantially prevented from contacting the point. Recess 70 also houses the suture material. An elevated flat surface 74 is located at the end of the container remote from recess 70.

A needle holder is shaped like a pair of long fine pliers with a handle locking mechanism. When a holder 68 fully loaded with needle 69 and a suture (not illustrated) is placed into container 67, the suture needle 69 sits below the middle sloping section 73 in a recess 70 and the width of recess 70 allows little fore and aft movement thus offering stability for the needle holder and its attached suture needle. Moreover the point of the suture needle is below the middle ramp section 73 thereby minimising the risk of a user's fingers accidentally coming into contact with the sharp needle. Because the middle ramp section 73 slopes

downwards towards the recess 70, the finger grips 75 of needle holder 68 are elevated above flat surface 74 thereby allowing user's fingers sufficient room to be inserted and facilitating removal of needle holder 68
5 from the container. The unit could be manufactured to suit a variety of needle holder sizes. The low rectangular design of the container provides stability when placed on a patient's person during an operation.

FIGS 4 and 4A illustrate a container 76 which can be
10 incorporated into container 67 (as seen in FIG 3) and which is adapted to contain a straight needle 77 and a suture 78 threaded thereto. Needle recess 79 is elongated and closed at one end 82. Container 76 also has a suture recess 83 for receiving suture 78 threaded
15 to needle 77. Needle recess 79 opens into suture recess 83 and edges 84,85 of suture recess wall 86 constitute guide means for guiding a user placing a straight needle in container 76 within needle recess 79. The arrangement is such that a straight needle received within the needle
20 recess is positioned therein such that the point of the straight needle is positioned within the needle recess such that a user's fingers are substantially prevented from contacting the needle point. The base of container 76 extends outwardly to provide wings 87,88 on either
25 side of the container. As seen in FIG 3, these wings facilitate a sliding drawer function when container 76 is incorporated in container 67. Handle 90 allows container 76 to be easily removed from the underside of the suture needle tray 67. The relatively wide baseplate formed by
30 wings 87,89 also provides stability enabling the container to be placed on a patient's person during an operation.

Suture recess serves the dual purpose of maintaining suture 78 in a sterile environment and provides
35 sufficient room for a user's fingers to grasp the blunt end of the needle. Straight suture needles are very fine and are therefore very light in weight. To ensure that the light needle does not become dislodged during

transfer, a small magnet 89 is positioned beneath needle recess 79.

The containers described above can be made from a range of suitable material as will be well known to those skilled in the art. If intended to be re-used they can be made from autoclavable plastic and will include sufficient steam ventilation holes for autoclaving purposes. Alternatively if intended to be disposable, they can be made cheaply from a suitable plastics material.

In use during surgical procedures, it will be appreciated that containers in accordance with the present invention utilise a principle conferring significant advantages over existing methods, systems and equipment. Sharp instruments are traditionally passed between surgeons, scrub nurses and other theatre staff either directly hand to hand, or by being placed in a container such as a conventional general purpose kidney bowl.

However in accordance with the present invention, the dangers of needle stick injury or other injury from a non-sterile sharp instrument which may have been invasively used on a patient are significantly reduced by utilising a specific purpose-designed container in which the sharp instrument is positioned by the transferor of the sharp instrument and from which the sharp instrument is removed by the transferee or receiver of the sharp instrument, the container of the present invention being such that the sharp instrument is received within an instrument recess and positioned therein such that the cutting portion of the instrument is not directed towards the opening of the instrument recess whereby the fingers of the transferor or transferee are substantially prevented from contacting the cutting portion.

The scalpel container provides substantial advantages and is an improvement on the traditional kidney tray which being an open topped dish gives little if any protection to users against accidental injury from

the scalpel blade. Injury from scalpel blades carry the possibility of an operator contacting a serious or fatal disease and the present invention significantly minimises this risk.

- 5 The present invention also improves upon the current method for storing scalpels on a scrub nurse's instrument trolley (which is simply to place them into an open kidney shaped dish or to leave them siting loosely on the sterile cloth drape which covers the instrument trolley).
- 10 Removing the blade and its handle from these kidney dishes involves the risks mentioned above, and storing them loosely on the drapes not only involves the same risk but also carries the risk of the sharp blade penetrating the cotton trolley drape and rendering the
- 15 blade tip unsterile. This would then render the cloth trolley unsterile as well and would also put the patient at risk of contracting an infection.

- The suturing needle container also has a number of significant advantages. Suture materials vary in length
- 20 and in elasticity and some modern materials are very loose and fall freely under gravity to their full length. In an operating theatre anything that falls below scrub nurse waist level is deemed to be unsterile and endangers the patient of contracting an intra-operative infection.
- 25 This frequently occurs with known methods of needle holder and suture transfer between surgeon and scrub nurse. Storing all the suture material in the dished recessed area of the tray avoids this problem. The tray also protects the patient against needle stick injury.
- 30 Often when the scrub nurse is busy, the surgeon if finished the operation will place a needle holder with a suture needle loaded onto it onto the drapes covering the patient. This can then penetrate the drapes and injure the patient. Personal transfer of a loaded needle holder
- 35 from one person to another, as commonly occurs in known systems, carries a high risk of needle stick injury. The suture tray of the present invention significantly minimises all these risks.

The physical transfer of straight needles between members of a surgical team also involves an extremely high risk of needle stick injury and this is also significantly minimised by the straight needle container of the present invention.

It will of course be realised that whilst the above has been given by way of an illustrative example of this invention, all such and other modifications and variations hereto, as would be apparent to persons skilled in the art, are deemed to fall within the broad scope and ambit of this invention as is herein set forth.

Claims

1. A container for holding a sharp instrument having a handle portion and a cutting portion, the sharp instrument being held within the container to be easily accessible during surgical procedures, said container including:-

an instrument recess adapted to receive at least the cutting portion of said sharp instrument, and
10 inclined guide means for guiding a sharp instrument placed in said container to said instrument recess;

the arrangement being such that a sharp instrument received within said instrument recess is positioned therein to be easily accessible for re-use during
15 surgical procedures and such that the cutting portion thereof is not directed towards the opening of the instrument recess whereby a user's fingers are substantially prevented from contacting said cutting portion.

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2. A container as claimed in claim 1, wherein said container includes inclined walls converging to said opening, the inclined walls constituting said guide means.

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3. A container as claimed in claim 1, wherein said instrument recess is elongated and closed at each end, is adapted to receive a scalpel and along two opposite lengths thereof has a cross sectional configuration of
30 width slightly greater than the major cross-sectional dimension of a scalpel and depth slightly greater than the minor cross-sectional dimension of a scalpel, the length of said instrument recess being such that the scalpel blade is located within one of said opposite
35 lengths irrespective of the position of the scalpel in the instrument recess.

4. A container as claimed in claim 3, wherein said

instrument recess has sidewalls and a base, the junctions thereof being radiussed such that a scalpel is disposed to rest in the recess with its major cross-sectional dimension parallel to said base.

5

5. A container as claimed in claim 3, and including access means for providing a user with access to the scalpel handle for removing the scalpel from said instrument recess.

10

6. A container as claimed in claim 5, wherein said access means includes a finger access recess, the cross sectional configuration of said finger access recess being such as to allow a user's fingers to contact the scalpel handle for removing the scalpel from said instrument recess, the position of said finger access recess being such that the scalpel blade is not located within said finger access recess irrespective of the position of the scalpel in the instrument recess.

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7. A container as claimed in claim 1, and including barrier means for preventing a user's fingers entering said instrument recess.

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8. A container as claimed in claim 7, wherein said barrier means constitutes the opening to said instrument recess, the width of said opening being such as to allow a scalpel to enter the recess but to prevent a user's fingers entering the recess.

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9. A container as claimed in claim 1, and including handle means whereby a user can hold the container.

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10. A container as claimed in claim 1, and including handle mounting means for mounting a detachable handle whereby a user can hold the container.

11. A container as claimed in claim 1, and including a

plurality of said instrument recesses each adapted to receive a scalpel therein.

12. A container as claimed in claim 1 and adapted to, 5 contain a suture needle holder and a suturing needle held thereby, wherein said instrument recess is substantially semi-cylindrical and adapted to receive said suturing needle.

10 13. A container as claimed in claim 1 and adapted to contain a straight needle and a suture threaded thereto, wherein said instrument recess is elongated and closed at one end and adapted to receive said straight needle, and including a suture recess for receiving said suture.

15 14. A container as claimed in claim 12, and including a container as claimed in claim 13.

20 15. A container for holding a scalpel during surgical procedures, said container including:-

an elongated scalpel recess closed at each end and adapted to receive a scalpel, and having two opposite lengths of cross-sectional configuration with width slightly greater than that of the major cross-sectional dimension of the scalpel and depth slightly greater than 25 that of the minor cross-sectional dimension of the scalpel, the length of said scalpel recess being such that the scalpel blade is located within one of said opposite lengths irrespective of the position of the scalpel in the scalpel recess, and

30 guide means for guiding a scalpel placed in said container to said scalpel recess;

the arrangement being such that a scalpel received within said scalpel recess is positioned therein such 35 that the scalper blade is not directed towards the opening of the scalpel recess whereby a user's fingers are substantially prevented from contacting the scalpel blade.

16. A container for holding a suture needle holder and a suturing needle held thereby during surgical procedures, the container including:-

5 a substantially semi-cylindrical needle recess, adapted to receive the suturing needle therein, and guide means for guiding a suturing needle held by a suture needle holder to said needle recess;

10 the arrangement being such that a suturing needle received within said needle recess is positioned therein such that the point of the suturing needle is positioned within the needle recess such that a user's fingers are substantially prevented from contacting the point.

17. A container for holding a straight needle and a suture threaded thereto, the straight needle and threaded suture being held within the container to be easily accessible during surgical procedures, the container including:-

20 an elongated needle recess closed at one end and adapted to receive a straight needle therein;

a suture recess for receiving said suture, and inclined guide means for guiding a straight needle placed in said container to said needle recess;

25 the arrangement being such that a straight needle received within said needle recess is positioned therein to be easily accessible for re-use during surgical procedures and such that the point of the straight needle is positioned within the needle recess such that a user's fingers are substantially prevented from contacting the point.

18. A method of transferring a sharp instrument having a handle portion and a cutting portion between operators during a surgical procedure, wherein:-

35 the transferor of the sharp instrument places the sharp instrument in an instrument recess in an instrument holding container, the sharp instrument being held within the container to be easily accessible during surgical

ptocedures, and

the receiver or transferee of the sharp instrument removes the sharp instrument from said instrument recess;

5 said instrument recess being adapted to receive at least the cutting portion of said sharp instrument, and said instrument holding container having inclined guide means for guiding a sharp instrument placed therein to said instrument recess, the arrangement being such that a sharp instrument received within said instrument recess
10 is positioned therein to be easily accessible for re-use during surgical procedures and such that the cutting portion thereof is not directed towards the opening of the instrument recess whereby an operator's fingers are substantially prevented from contacting said cutting
15 portion.

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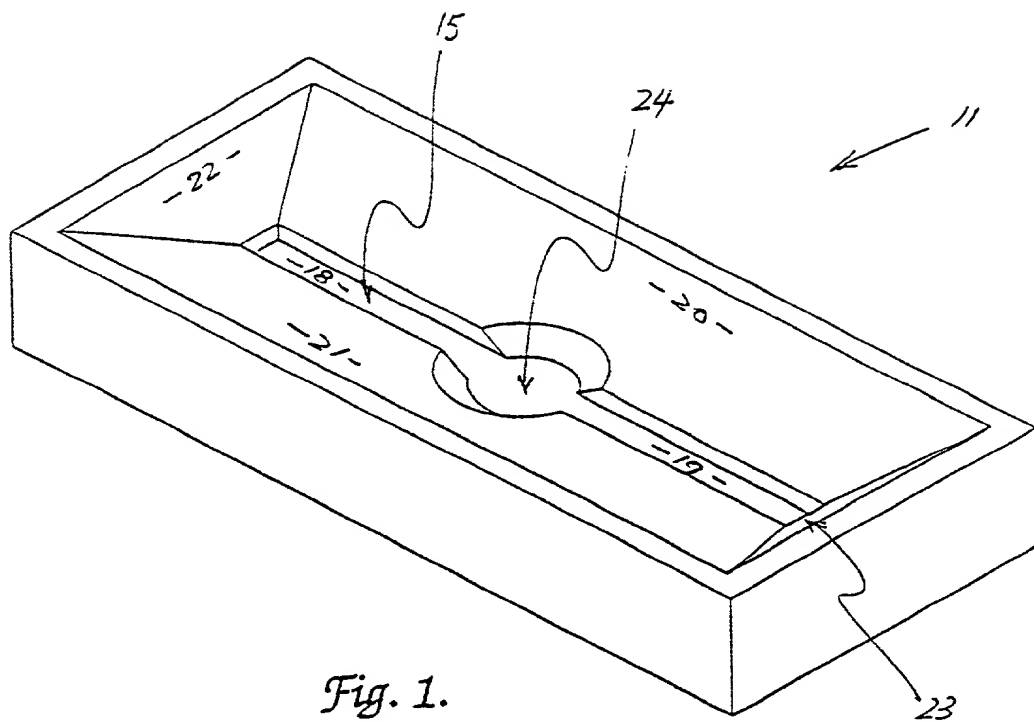


Fig. 1.

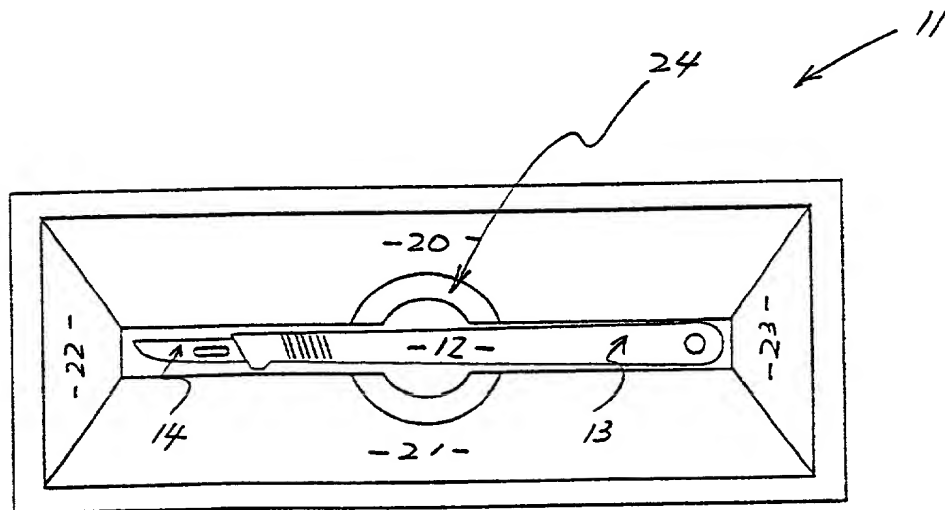


Fig. 1A.

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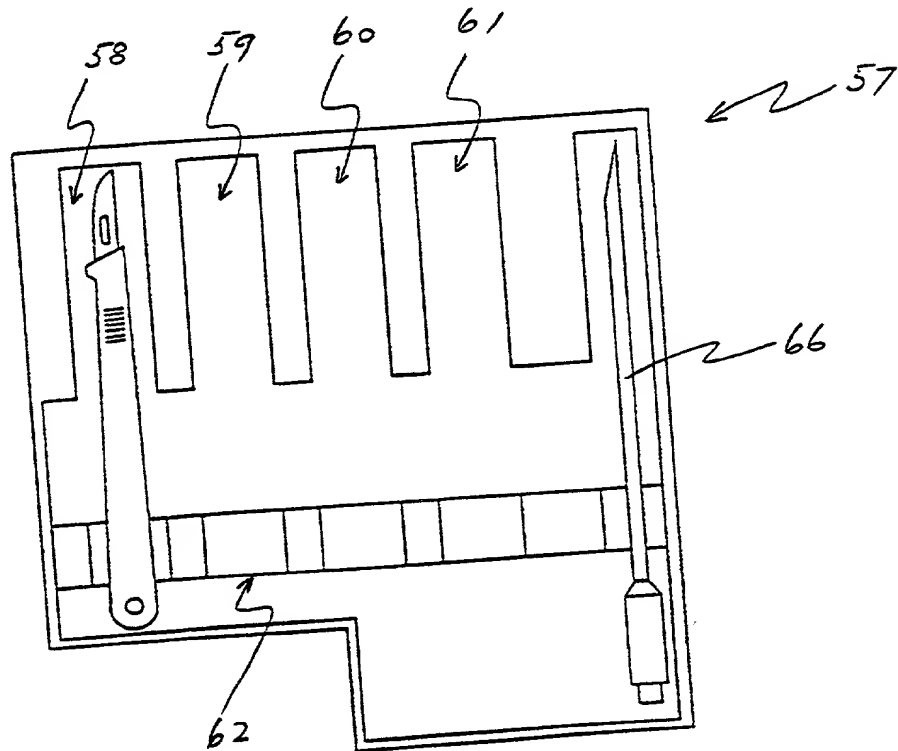
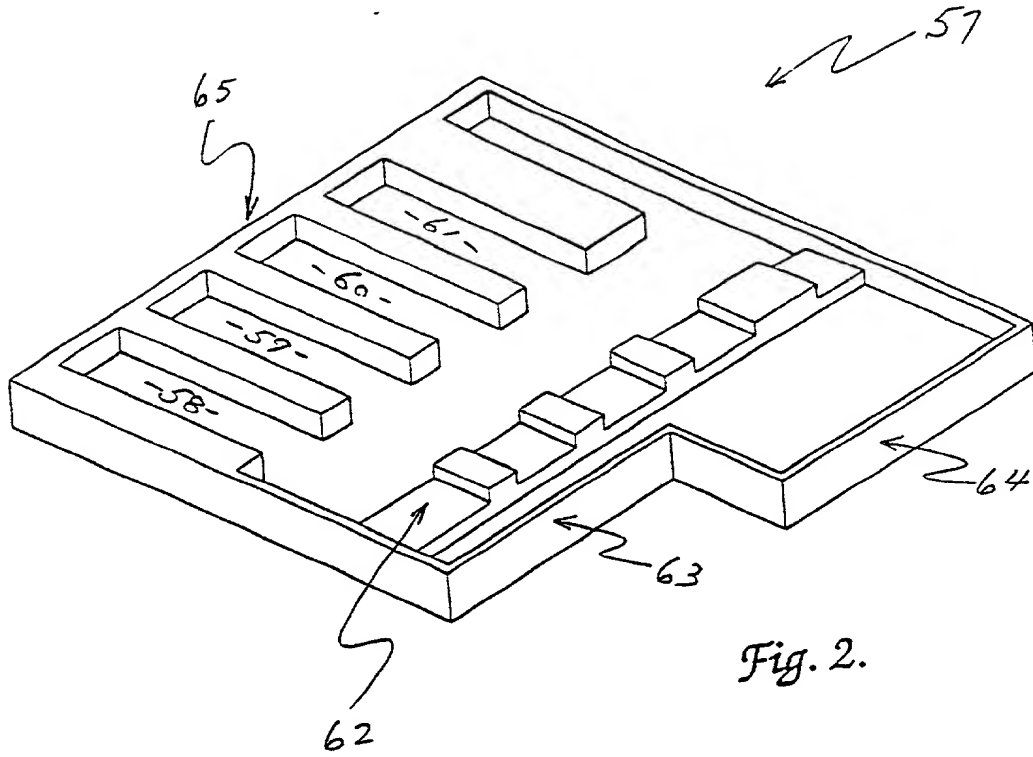


Fig. 2A.

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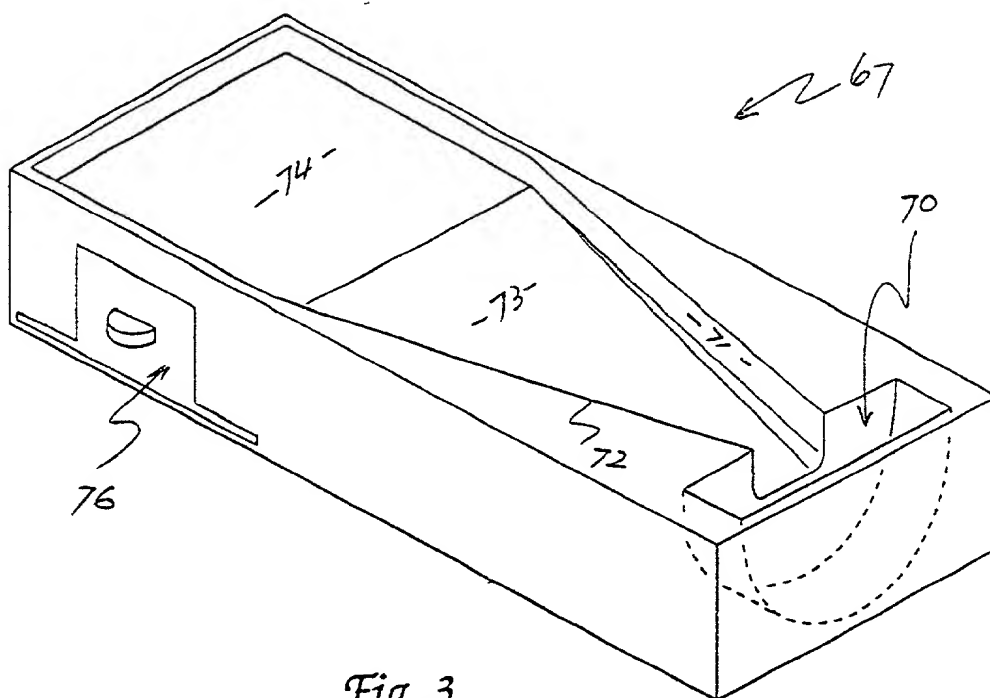


Fig. 3.

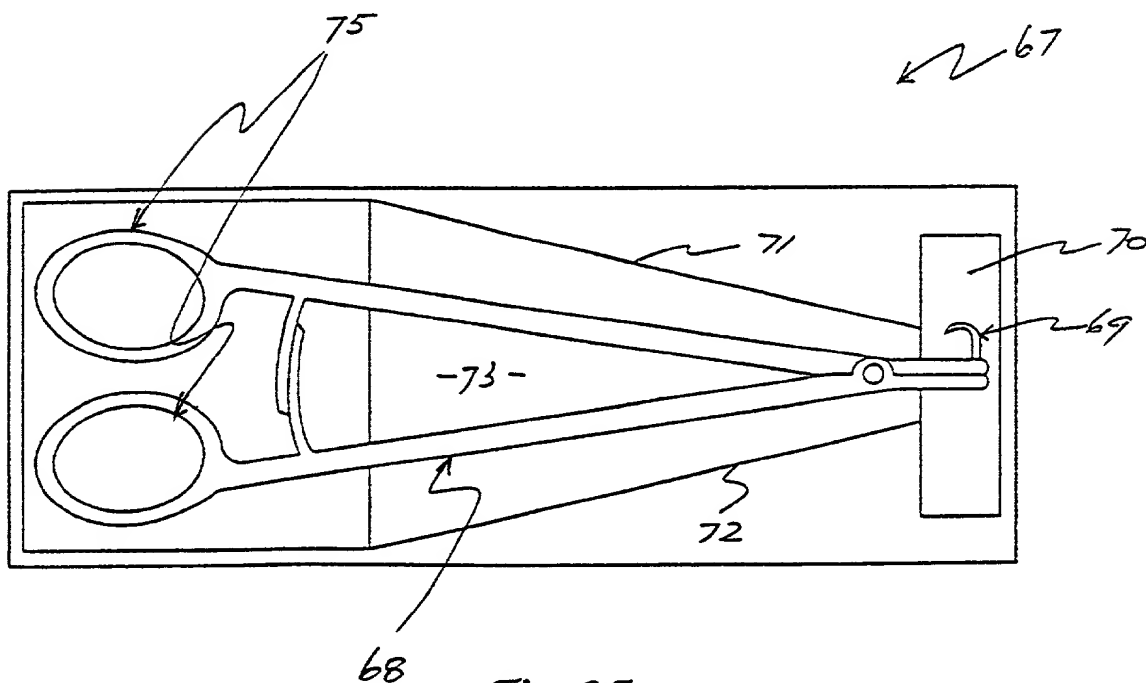


Fig. 3A.

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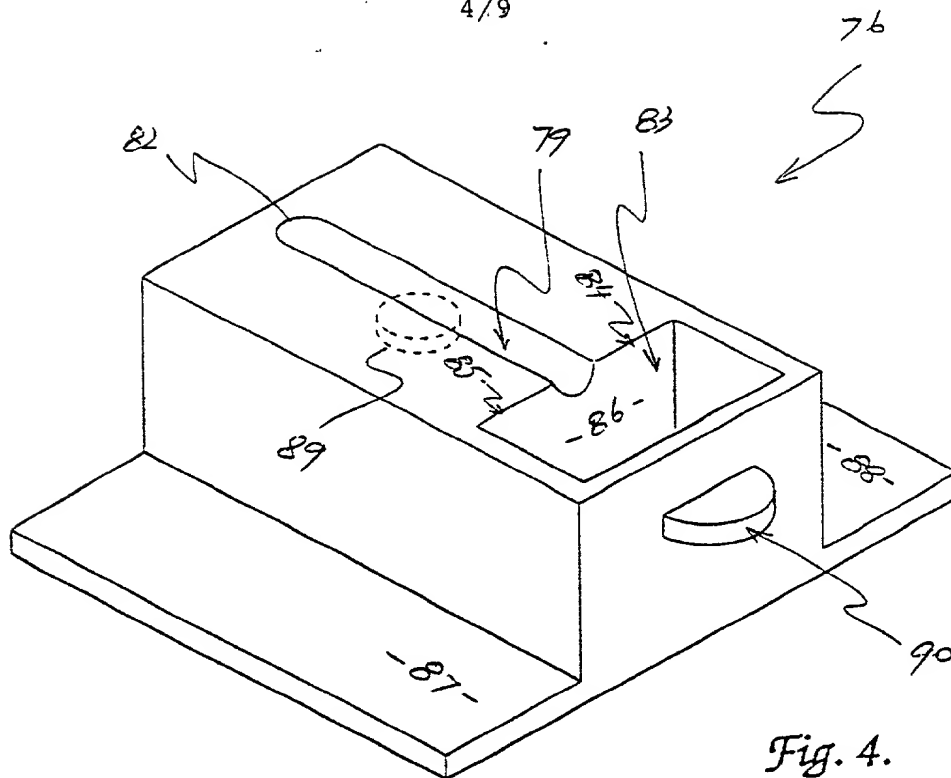


Fig. 4.

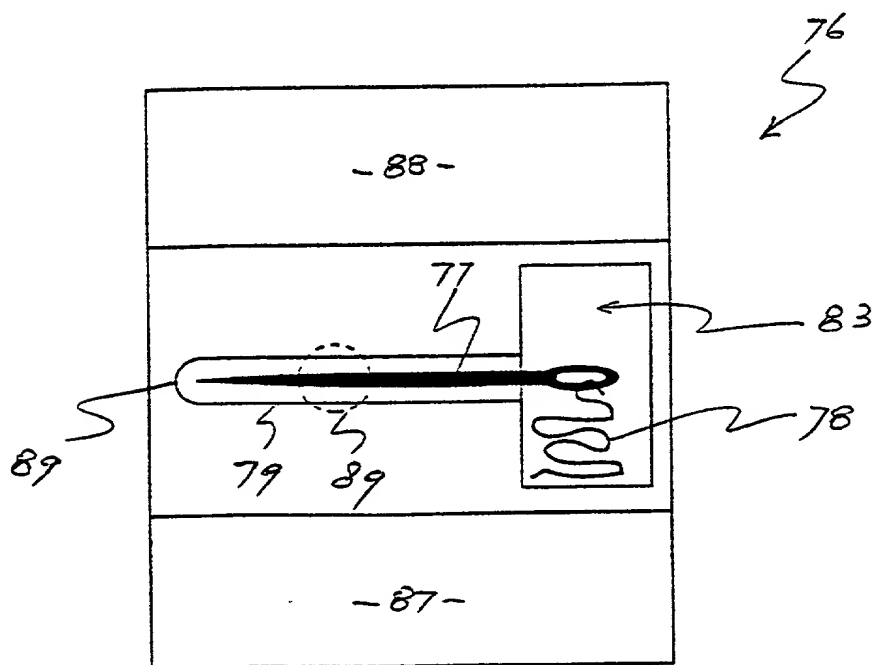


Fig. 4A.

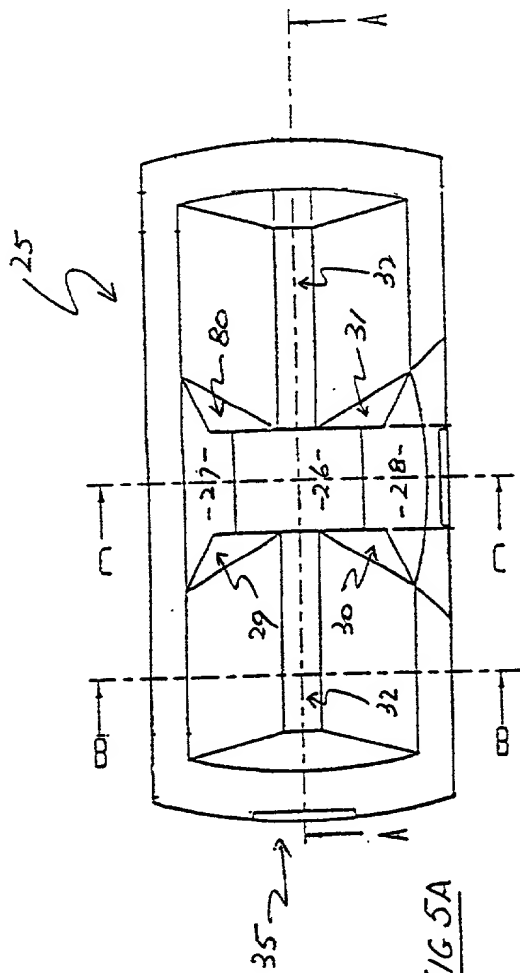


FIG 5A

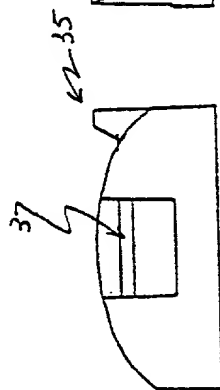


FIG 5B

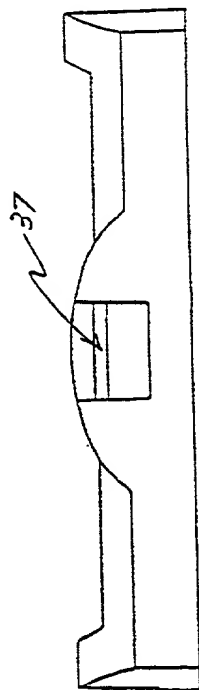


FIG 5C



FIG 5D

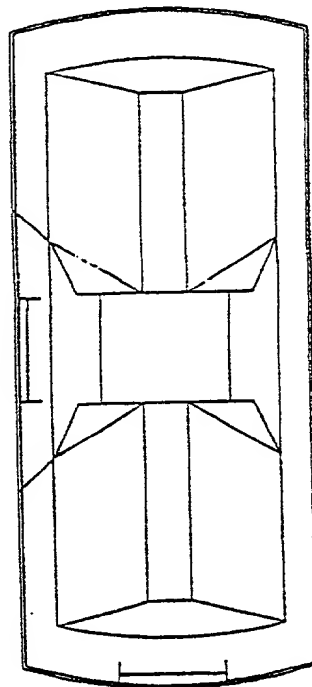


FIG 5E

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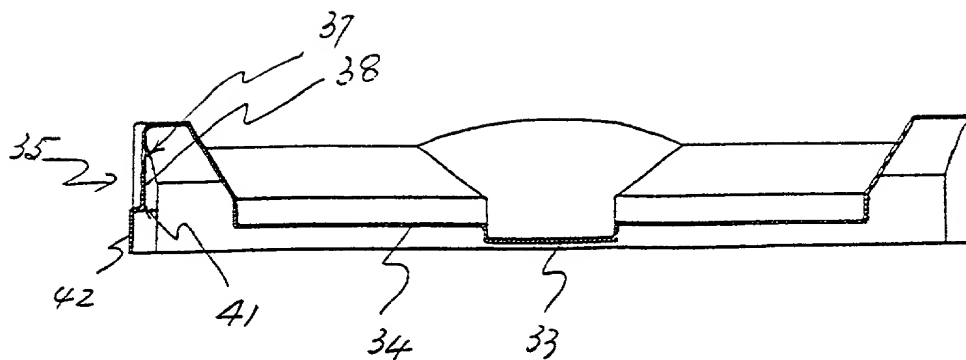


FIG 6A

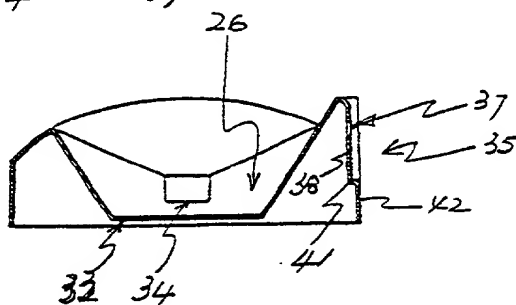


FIG 6C

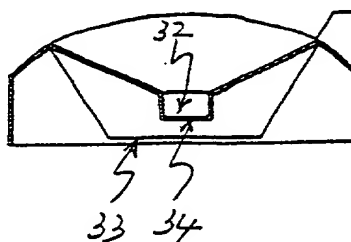


FIG 6B

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FIG 7A

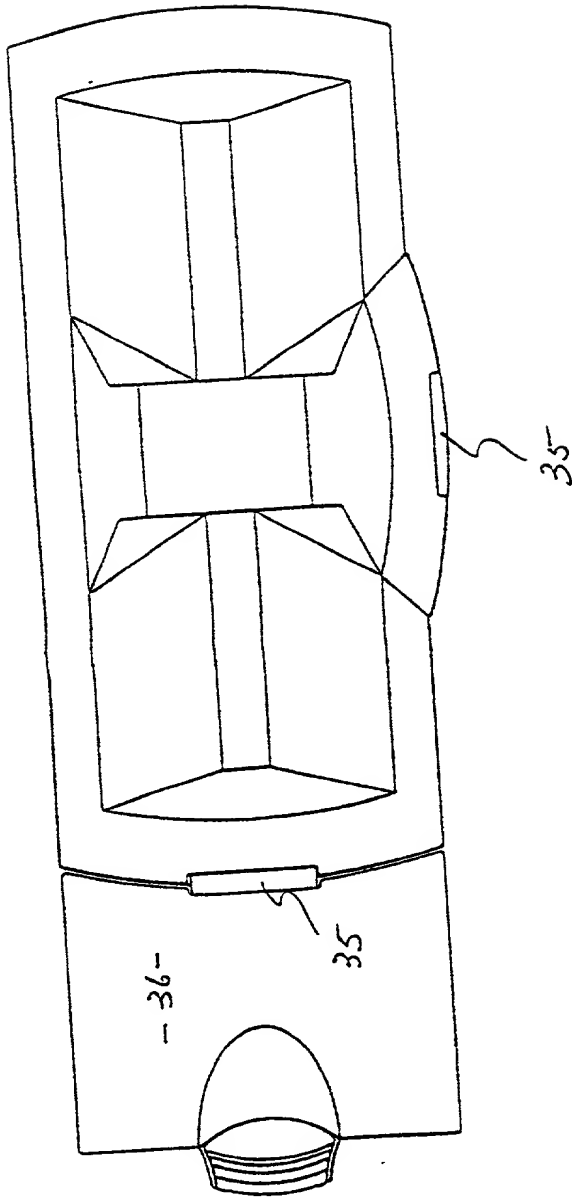
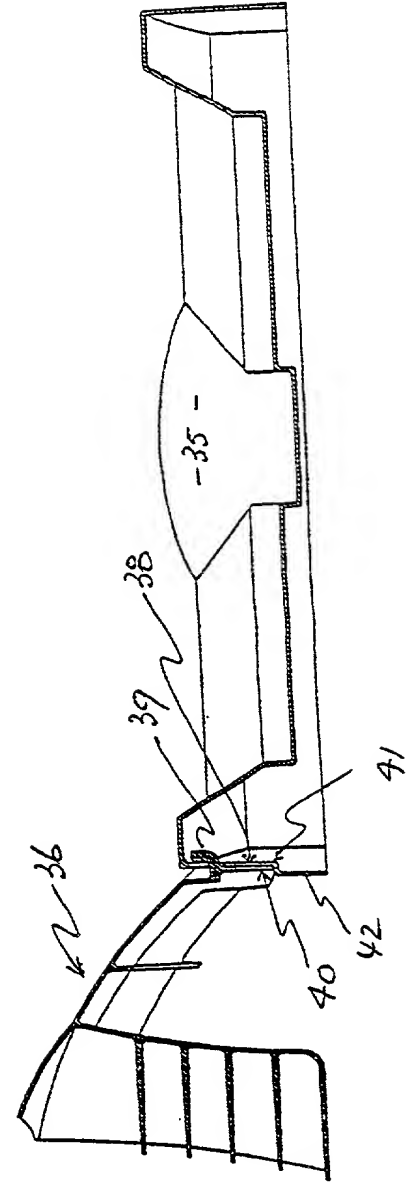


FIG 7B



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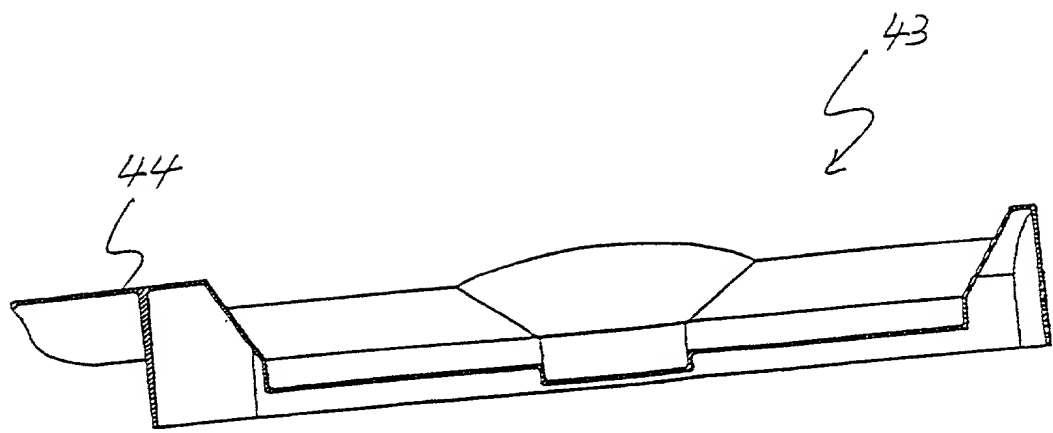


FIG 8A

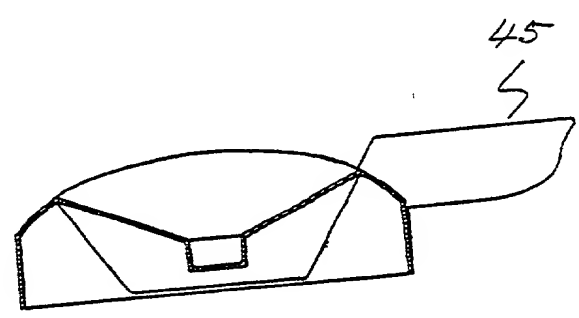


FIG 8B

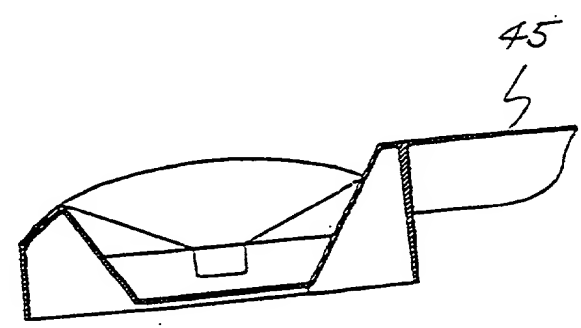


FIG 8C

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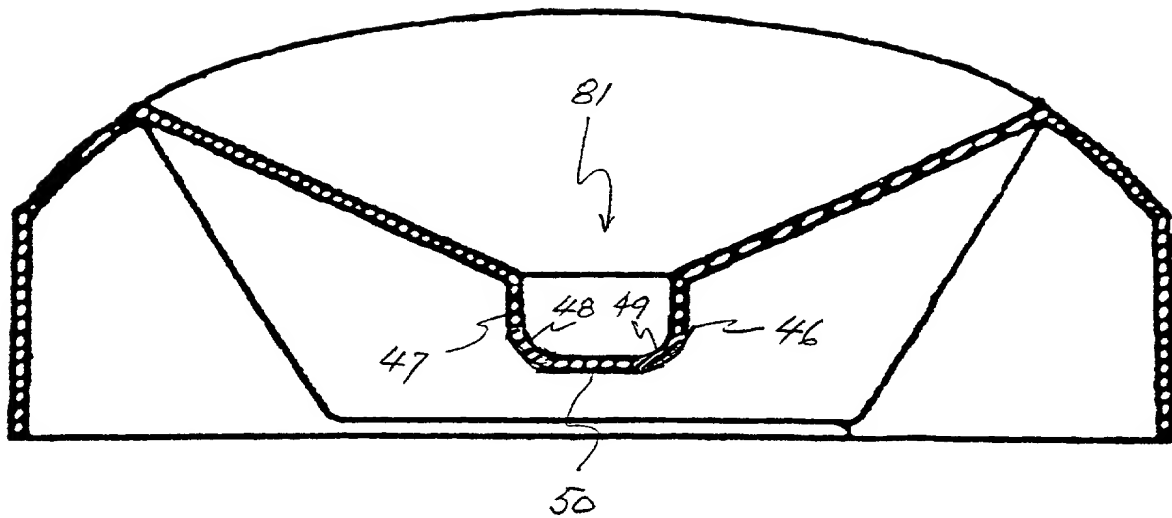


FIG 9

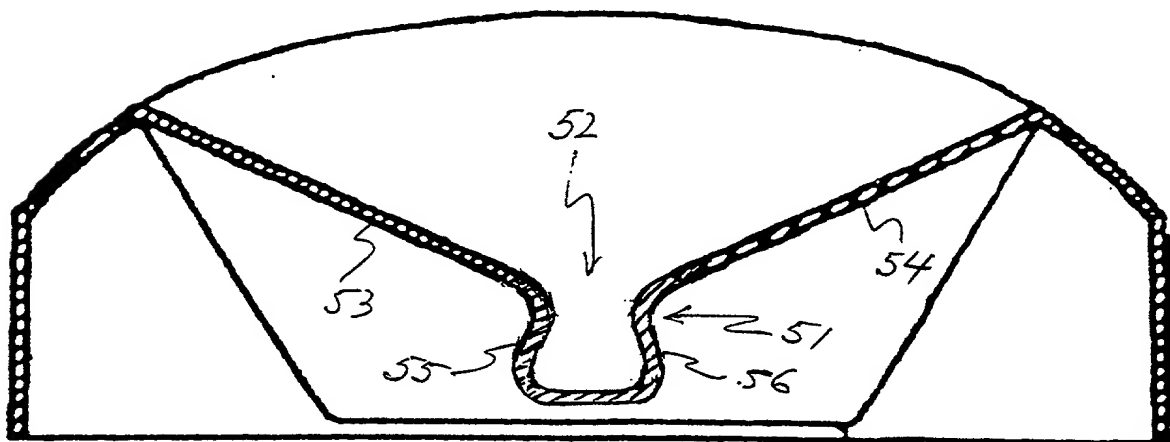


FIG 10

DECLARATION AND POWER OF ATTORNEY - PATENT APPLICATION

As a below named inventor, I hereby declare that I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought in the application entitled:

CONTAINER FOR SHARP INSTRUMENTS

specification of which _____, the
(check one) XX is attached hereto
XX was filed on 29 April 1997 as
United States Application Serial No. _____ or
PCT International Application No. PCT/AU97/00259
and was amended on 13 February 1998 and 26 February 1998
(if applicable)

I hereby declare that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to herein.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate on which priority is claimed (as listed below) and I have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

| Prior Foreign Application(s) | (AU) | (30.04.96) | Priority Claimed |
|------------------------------|------------------|------------------------|------------------|
| <u>PN 9597</u> | <u>Australia</u> | <u>30 April 1996</u> | <u>XX</u> |
| (Number) | (Country) | (Day/Month/Year Filed) | Yes No |
| _____ | _____ | _____ | Yes No |
| (Number) | (Country) | (Day/Month/Year Filed) | Yes No |
| _____ | _____ | _____ | Yes No |
| (Number) | (Country) | (Day/Month/Year Filed) | Yes No |
| _____ | _____ | _____ | Yes No |

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(b) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

| | | |
|-----------------------------------|------------------------|---|
| _____ (Application Serial No.) | _____ (Filing Date) | _____ (Status-patented, pending, abandoned) |
| _____ (Application Serial No.) | _____ (Filing Date) | _____ (Status-patented, pending, abandoned) |
| _____ (Application Serial No.) | _____ (Filing Date) | _____ (Status-patented, pending, abandoned) |
| _____ (Application Serial No.) | _____ (Filing Date) | _____ (Status-patented, pending, abandoned) |

I hereby appoint William R. Coffey, Reg. No. 24023; Jerry E. Hyland, Reg. No. 20904; Richard D. Conard, Reg. No. 27321; Steven R. Lammert, Reg. No. 27653; Richard A. Rezek, Reg. No. 30796; Timothy E. Niednagel, Reg. No. 33266; John P. Breen, Reg. No. 38833; Jill L. Werling, Reg. No. 39874; Nancy J. Harrison, Reg. No. 27083; R. Trevor Carter, Reg. No. 40549;

RECEIVED "1997 APR 30"

Dilip A. Kulkarni, Reg. No. 27510; Perry Palan, Reg. No. 26213; Mark M. Newman, Reg. No. 31472; Bobby B. Gillenwater, Reg. No. 31105; Paul B. Hunt, Reg. No. 37154; Michael S. Gzybowski, Reg. No. 32816; and Robert D. Null, Reg. No. 40746, as attorneys of record with full power of substitution and revocation, to prosecute this application, and to transact all business in the Patent and Trademark Office connected therewith, and I specify that communications regarding the application be directed to:

BARNES & THORNBURG
11 South Meridian Street
Indianapolis, Indiana 46204
Telephone (317) 236-1313

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Michael Shane CAVANAGH

Full Name of Sole or First Joint Inventor

Australia

Country of Citizenship

Inventor's Signature

Date

301 Lieutenant Bowen Drive
Bowen Mountain NSW 2753
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Residence and Post Office Address

Full Name of Second Joint Inventor, if any

Country of Citizenship

Second Inventor's Signature

Date

Residence and Post Office Address

Full Name of Third Joint Inventor, if any

Country of Citizenship

Third Inventor's Signature

Date

Residence and Post Office Address

Full Name of Fourth Joint Inventor, if any

Country of Citizenship

Fourth Inventor's Signature

Date

Residence and Post Office Address

Additional inventors to be similarly identified on attached sheet.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group:
 Attorney Docket No.: 20253-60398
 Applicant or Patentee: ~~XXXXXX~~ Michael Shane CAVANAGH
 Invention: CONTAINER FOR SHARP INSTRUMENTS

Serial ~~XXXXXX~~ No.:
 Filing ~~XXXXXX~~ Date: Herewith

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
 (37 CFR 1.9(f) AND 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(h) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled CONTAINER FOR SHARP INSTRUMENTS described in

- ☒ the specification filed herewith.
☐ application serial no. _____, filed _____
☐ patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ No such person, concern or organization
☐ Each such person, concern or organization listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____

ADDRESS _____

[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Michael Shane CAVANAGH

NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR

Signature of Inventor *MS Cavanagh* Signature of Inventor Signature of Inventor

Date 30/6/98 Date Date